Assessment of the Efficacy and the Impact of the Rapid, Practical and Ergonomic DOAC & Platelets Filter Device on Thrombin Generation Assay

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Conclusions: The TEG®6s system can improve diagnostic accuracy with a high degree of correlation to the Clauss assay. By using complementary data from CFF.MA (particularly above the RR for the other assays) and CK.MA a more complete assessment of hemostasis can be obtained.

PB0151 | The New QXpert Analyser Is Suitable for Routine Use in High Volume Haemostasis Laboratories

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Background: The QXpert (Grifols) is a recently launched fully automated, random access, cap piercing analyser using clotting, chromogenic and immunoturbidometric methods suitable for high volume laboratories. Liquid PT/INR (recombinant human tissue factor), APTT (ellagic acid/synthetic phospholipids) and fibrinogen (human thrombin) reagents are available for ease of use.

Aims: We have evaluated the QXpert for routine use in comparison to a widely used alternative system as recommended by CLSI.

Methods: We compared QXpert with CS5100 (Sysmex) with the following: PT/INR; liquid human recombinant thromboplastin (DG-PT RecombiLIQ) vs Innovin (Siemens): APTT; liquid ellagic acid APTT (DG-APTT Synth) vs Actin FS: Fibrinogen; liquid human thrombin reagent (DG-FIB L Human) vs Siemens Thrombin: Ddimer; Latex assay (Grifols) vs Innovance. The following groups were studied: normal subjects (n= 21-53); warfarinised patients (n = 134); subjects with congenital deficiency states (n= 43 intrinsic defects): acquired coagulation disorders such as liver disease/DIC/critical care (n= 33).

Results: Table 1 shows mean INRs results. There was no significant difference between INRs with the two systems for subjects with INRs < 4 when all data were combined. Differences observed at higher INRs were unlikely to be clinically relevant. Of 23 cases with isolated FVIII or FIX deficiency (including 11 with FVIII or FIX between 0.30 and 0.56 IU/ml) only 1 case (FIX 0.41 IU/ml) had a normal APTT with DG-APTT Synth. There was no significant difference and a good correlation between fibrinogen results and between DDimer results by the 2 methods in normal subjects/Liver disease/DIC.

Conclusions: Sensitivity to deficiency of FVIII and FIX was excellent and INRs were in acceptable agreement with a widely used method. The QXpert is suitable for routine use in high throughput laboratories in combination with liquid reagents from Diagnostic Grifols.

PB0152 | Assessment of the Efficacy and the Impact of the Rapid, Practical and Ergonomic DOAC & Platelets Filter Device on Thrombin Generation Assay

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Background: Thrombin generation assay (TGA) is known to be highly sensitive to direct oral anticoagulants (DOACs). It provides more information thank to its capacity to explore in more details the kinetic formation of thrombin. Devices with adsorbent properties that are used to remove DOACs from plasma samples are usually known to interfere with TGA parameters at normal tissue factor (TF) concentration (i.e. 5 pM of TF) by increasing the peak, the mVRI and by reducing the time-to-peak. This prevents the use a ratio of the conditions before/after removal of DOAC to assess the intensity of anticoagulation at the individual patients' level.

Aims: To assess the efficacy and the impact of the DOAC & Platelets Filter (DP-Filter) device from the University of Namur on TGA parameters from plasma spiked with DOACs.

Methods: Normal pooled plasma (NPP) was mixed with apixaban, betrixaban, dabigatran, edoxaban or rivaroxaban at concentrations of 0-100-300-1000 ng/ml. Plasma were tested before and after filtration on the calibrated automated thrombogram using the PPP-high reagent (20 pM of TF).

Results: All DOACs affect TGA parameters. Filtration with DP-Filter efficiently restores baseline value of the lag time at 105±9% and the ETP at 93±9% for all DOACs whatever the concentration. The peak parameters are restored with DP-Filter at 98±7% for edoxaban, rivaroxaban and betrixaban. However, it seems that the device is not

TABLE 1 INRs with DG-PT RecombiLIQ and Innovin

Group	n	Mean INR - RecombiLIQ/QXpert	Mean INR Innovin/CS5100	Difference (RecombiLIQ-Innovin	Significance Paired t test
INRs <2.0	21	1.65	1.62	2%	ns(p=0.77)
INRs 2-2.4	20	2.24	2.23	<1%	ns(0.87)
INRs 2.5-2.9	22	2.71	2.80	-3%	ns(0.17)
INRs 3.0-3.4	28	3.19	3.42	-7%	p<0.0001
INRs 3.5-4.0	20	3.69	4.15	-12%	p<0.0001
All INRs <4.0	111	2.72	2.87	-5%	ns(p=0.16)
INRs >4.0	23	4.69	5.80	-19%	p=0.01

able to totally restore initial peak in plasma samples spiked with apixaban and dabigatran (75±20% and 83±7%, respectively).

Conclusions: DP-filter device is effective in removing DOACs from plasma. It allows to recover the baseline TGA profile of the NPP. The use a ratio of the conditions before/after removal of DOAC appears to be feasible using reagents with high TF content. It could provide interesting information on the level of anticoagulation at the individual patient's level.

PB0153 | Thromboelastography Cartridge-based System Measurements Reflect Both Platelet Count and Function Contribution to Clot Formation: An Ex-vivo Evaluation

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Background: Low platelet count remains the trigger for platelet transfusion in multiple guidelines; however, there is an increasing body of evidence supporting a more comprehensive assessment of coagulation. Studies have shown that using thromboelastography to guide transfusion can improve outcomes compared with conventional coagulation assay protocols.

Aims: To determine if the new cartridge-based TEG®6s can accurately evaluate the contributions of both platelet count and platelet function (aggregation) to maximum clot strength.

Methods: TEG®6s assays were performed on whole blood samples from eight healthy volunteers to determine platelet count (n=5) and platelet function (n=5). Maximum amplitude (MA) was assessed for functional fibrinogen (CFF), RapidTEG® (CRT), Kaolin (CK) and Kaolin with heparinase (CKH). Platelet count was measured using complete blood count. Abciximab was used to inhibit platelet aggregation, and platelet function was evaluated by light transmission aggregometry (LTA) with TRAP agonist. The relationship between TEG®6s parameters and platelet count values or concentration levels of abciximab was studied in the framework of generalized linear or nonlinear models.

Results: There was a positive correlation between platelet count and CK.MA, CRT.MA and CKH.MA ($p< 0.0001$). Abciximab concentration displayed an inverse relationship with CK.MA, CRT.MA, and CKH.MA ($p< 0.001$); no significant relationship was observed with CFF.MA ($p=0.24$). Platelet count reduction effects could be measured for concentrations < 92 platelets/µL for CK.MA, < 74 platelets/µL for CRT.MA, and < 87 platelets/µL for CKH.MA. Furthermore, platelet function inhibition could be detected by all three assays at levels >66% as measured by LTA.

Conclusions: These results demonstrate that the TEG®6s system can be used to accurately evaluate platelet count and function at the point of care, providing a comprehensive overview of platelet contribution to coagulation. Further trials are needed to elucidate the clinical benefit of TEG®6s guided platelet transfusions versus platelet count alone.

PB0155 | Inter-reagents Agreement of D-dimer Test Results in the Low Range of Concentrations

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Background: Main indications for D-dimer testing include diagnosis of DIC and exclusion of VTE diagnosis. Recently, D-dimer was found valuable in guiding the duration of anticoagulation after a thrombotic event. In that respect, the "HERDOO2" clinical decision rule to guide duration of anticoagulation in women with unprovoked VTE includes Hyperpigmentation, Edema, Redness of lower extremity, Vidas D-Dimer≥250 ng/mL, Obesity, and Older age≥65 years.

Aims: As D-dimer assays are not standardized, the aim of the present study was to evaluate the inter-reagent agreement of results in the low range of concentrations.

Methods: For that purpose, we investigated plasma samples from 50 patients (31 males and 30 females, mean age=34 years, range:18-72) in whom D-dimer testing was prescribed for VTE exclusion. D-dimer was evaluated using 4 different quantitative automated latex agglutination-based assays: HemosIL D-dimer HS500 (Werfen),HemosIL Accustar D-dimer (Werfen),Innovance D-dimer (Siemens),STA-Liatest D-dimer (Stago), and with the Vidas D-dimer Exclusion II (BioMérieux).

Results: Test results (Table) were well correlated with those obtained with the Vidas ($r^2>0.40$, except for one reagent).

The concordance of test results below or above the cut-off level of 250 ng/mL (270 for Liatest, as its limit of quantitation) assessed

TABLE 1

	HemosIL D-dimer HS500	HemosIL AcuStar D-dimer	Innovance D-dimer	STA-Liatest D-dimer	Vidas D-dimer Exclusion II
D-dimer (ng/mL FEU) Median (range)	224 (<203 - 402)	209 (83 - 570)	345 (<170 - 630)	300 (<270 - 710)	244 (121 - 536)
r2 (with Vidas)	0.403	0.417	0.201	0.483	-
Concordance with Vidas <250 ng/mL	Kappa=0.608	Kappa=0.448	Kappa=0.295	Kappa=0.608 (using 270 ng/mL)	-